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01-0604



1753

Case No. 069.00 (0225-0069.30)

IN THE UNITED STATES PATENT AND TRADEMARK OFFICE

Inventor(s): Lackritz et al

Serial No: 09/911,033

Filed: 20 July 2001

For: IMPROVED METHODS AND
DEVICES FOR CONDUCTING
ELECTROPHORETIC
ANALYSIS

RECEIVED

JAN 13 2004

TC 1700

Examiner: K. Olsen

Art Unit: 1753

Declaration under 37 C.F.R. 1.131
by Dr. Hilary S. Lackritz

Commissioner for Patents
P.O. Box 1450
Alexandria, VA 22313-1450

Sir:

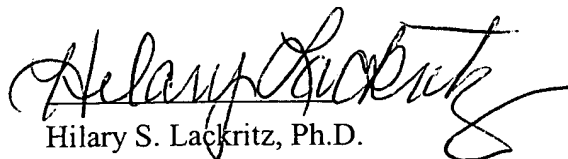
I, the undersigned, Hilary S. Lackritz, declare as follows:

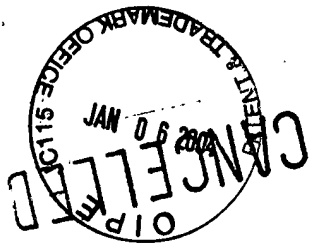
1. From November 29, 1999, until January 4, 2002, I was employed by ACLARA Biosciences, Inc., as a principal scientist and associate director to design and develop microfluidics devices.
2. I am an inventor in the above patent application, Ser. No. 09/911,033, and have read the portions of the Office Action dated 25 August 2003 in which the Examiner rejected the claims as described below:
 - (i) claims 1-5 were rejected under 35 U.S.C. 102(e) as being anticipated by certain disclosures in Tan et al, U.S. patent application Ser. No. 09/847,780 filed May 1, 2001 ("Tan application") with priority based on U.S. provisional application 60/201,575 filed on May 1, 2000, and published as U.S. patent publication 2002/00229968 A1; the Examiner alleged that the invention described by claims 1-5 was described in the Tan application, which was filed by another prior to the invention of the subject matter of claims 1-5; and
 - (ii) claims 1-5 were rejected under 35 U.S.C. 103(a) based on Ramsey, U.S. patent 6,010,608, in view of either the Tan application or Bjornson et al, U.S. patent application Ser. No. 09/995,909 filed November 28, 2001 ("Bjornson

application”) and published as U.S. patent publication 2002/0092767, which application is a continuation of U.S. patent application Ser. No. 09/557,519 filed on April 25, 2000, which, in turn, is a continuation-in-part of U.S. patent application Ser. No. 09/153,814 filed September 15, 1998, issued as U.S. patent 6,284,113.

2. I conceived of the use of polynorbornene based polymers in microfluidics devices claimed in the above patent application on or before March 7, 2000, and therefore, before the priority dates of either the Tan application (May 1, 2000) or the Bjornson application (April 25, 2000). This conception is shown by the invention disclosure set forth on pages 79 and 80 of my laboratory notebook No. 1099, true copies of which are attached as Exhibit A. On page 79, next to circled item “2” near the middle, “zeonor” is listed as a microfluidic substrate, and on page 80, second sentence, I state, “The Polaroid material Transplan is a polynorbornene, like Zeonor, so all processing should be compatible” in reference to the use of these materials for making microfluidics devices. As disclosed in paragraph 0021 of the publication of the above application, Zeonor is a brand name of a commercially available polynorbornene based polymer.
3. From the date of conception until the filing of provisional application Ser. No. 60/220,059, work was continuously and diligently carried out to reduce the invention to practice, as evidenced by (i) the series of emails dated April 13, 2000, a true copy of which is attached as Exhibit B, and (ii) pages 139 and 140 of my laboratory notebook No. 1099 dated April 24, 2000, true copies of which are attached as Exhibit C. The series of emails in Exhibit B describes communications among employees of ACLARA Biosciences relating to the project to make a microfluidics device of the invention. The communications include a report by Mr. Bart Borland that a substrate portion of a microfluidics device of the invention had been molded. Other communications relate to the lamination of a cover piece to the substrate to complete the device. On page 140 of my laboratory notebook notes are recorded from a “Zeonor applications meeting” that relate to the manufacture of a microfluidics device of the invention.
3. I further declare that all statements made herein of my own knowledge are true and all statements made on information and belief are believed to be true; and further that these statements were made with the knowledge that willful false statements and the like so made are punishable by fine or imprisonment, or both, under Section 1001 of Title 18 of the United States Code, and that such willful false statements may jeopardize the validity of the application or any patent issued thereon.

12/17/03
Date


Hilary S. Lackritz, Ph.D.



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NOTEBOOK NO. 1099

ISSUED TO Hilary Lackritz

ON 11/30/99

DEPARTMENT _____

RETURNED 7/18/00

SCIENTIFIC NOTEBOOK COMPANY
2831 LAWRENCE AVENUE
STEVENSVILLE, MICHIGAN 49127
800-537-3028
<http://www.snco.com>

EXHIBIT "A"

From Page No. _____

Invention Disclosure

Web-coated multilayered device for microfluidics -
Conductive electrodes. Real-time prototyping.

Use, for example, Polaroid's plastic film conductor
(formed by a dry digital laser etching system -
direct write) to pattern the conductive electrodes
for microfluidics.

You can then

1. pattern channels around this
2. coat patternable material on top & cure.
3. laminate layer on top

with microfluidic structures defined.
This would give you an all-plastic web coated
device that is cost effective & straightforward to
laminate and very stable.

Thus

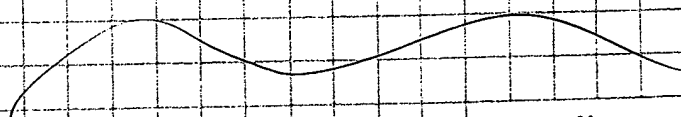
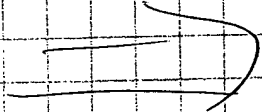
- ① define electrodes using polaroid film.
- ② laminate Zenor (or other) film micro-
fluidic substrate aligned such that
the electrodes and channels are correctly
aligned
- ③ package

Can use roll to roll processing to do the high yield
processing.

Developed for lightweight plastics display -
by Polaroid/DARPA consortium - should work well
for microfluidics field as well!

(Note that the antireflection film info might be
useful for several detector configurations!)

continued -



T Pag No. _____

Witnessed & Understood by me,

Date

7/8/00

Invented by

Date

3/7/00

Recorded by

From Page No. _____

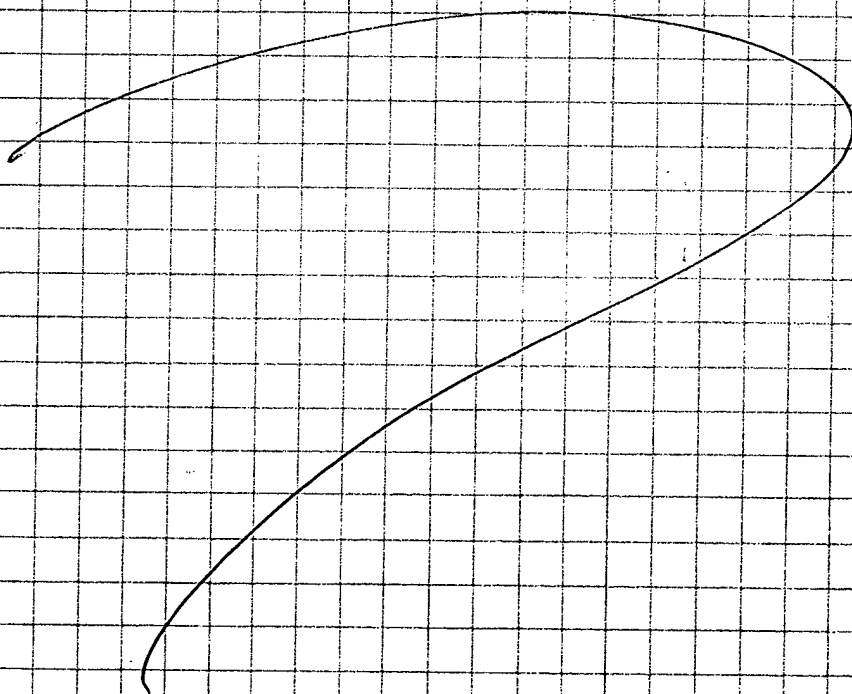
I've never heard of anyone considering such a project - we wouldn't need to metallize the plastics or cope with any of the process problems that are often an issue.

The Polaroid material, Transphane, is a polymer - polyene, like Zephor, so all processing should be compatible. (?)

We could use this type of technology for rapid prototyping -

one-ups of electrodes, etc.
patterning structures

More details to be provided.



To Page No. _____

Witnessed & Understood by me,

J. Gibbs

Date

3/8/00

Invented by

Recorded by

Henry Dickins

Date

3/7/00.

TITLE

Lackritz, Hilary

From

From: Nguyen Uyen
S nt: Thursday, April 13, 2000 4:59 PM
To: Moyer, Kristina Granlund
Cc: Lackritz, Hilary; Maher Kevin
Subject: RE: Zeonor 1420R Samples

I gave Kevin 8 coins
2 coins zeonor with 1020 40um
2 coins zeonor with 1020 100um
2 coins zeonor with 1420 2 mil
2 coins zeonor with 1420 4 mil
1020 film seal fine with zeonor coins, but 1420 the film is too rough and cannot be sealed very well due to the pattern on the film

-----Original Message-----

From: Moyer, Kristina Granlund
Sent: Thursday, April 13, 2000 1:50 PM
To: Nguyen Uyen
Subject: FW: Zeonor 1420R Samples

Hi Uyen,

Kevin says he needs only 2 or 3 Zeonor Claracoins to do his evaluation. Do you have time to do this lamination, or should I ask Thai?

Thanks,

Kristina

-----Original Message-----

From: Slomski Dennis
Sent: Thursday, April 13, 2000 12:37 PM
To: Borland Bart
Cc: Lackritz, Hilary; Moyer, Kristina Granlund
Subject: RE: Zeonor 1420R Samples

CLARACOINS. SEE SHEET-2 (ID-4) IN THE LABCARD INVENTORY (10000013-01) @ I:\Controlled Documents.
THAI CAN LAMINATE IF A LABCARD ORDER IS INITIATED BY HILARY OR KRISTINA.

-----Original Message-----

From: Borland Bart
Sent: Thursday, April 13, 2000 12:26 PM
To: Lackritz, Hilary
Cc: Slomski Dennis; Maher Kevin
Subject: Zeonor 1420R Samples

I extruded Zeonor 1420R this morning and have 2 and 4 mil samples for you. The samples are clear, however, there are flow or die lines in them. Kevin says he can determine if they will interfere with side detection if we can give him a laminated piece. Do we have molded Zeonor parts that can be laminated? Let me know.

I have placed the samples on you chair.

Bart Borland
Sr. Plastics Engineer
Aclara BioSciences
1288 Pear Ave.
Mountain View, CA 94043
650 210-1203 FAX 650 210-1210

TITLE _____

Book No. _____

From Page No. _____

Venice
GA bufferNaTAPS
acid/base

stability studies

FTIR - degradation

Zeonor chip

immersion oil 42°C, 45°C

silicone oil -

reverse immersion

cloudy -
crazing

FTIR testing

Zeonor + 2-pyrrolidinone

GA buffer

immersion oil

To Page No. _____

Witnessed & Understood by me,

Date

Invented by

Recorded by

Date

4/24/00

from Page N _____

4/24/00 Leoner applications meeting

4/24/00 Dennis (Davis, Claudia, Tony)

Thin electroforms

residual σ (T, i, j)

compressive & tensile

fixturing has a significant effect

up to now 1/4" thick

thicker for injection molding

L/D issue for core pin

Ni - 22 RC 10,000 - 50,000 cycles

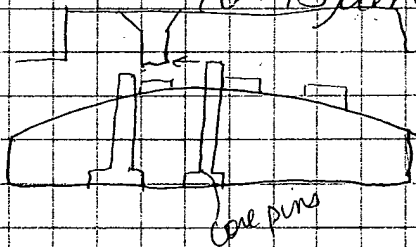
\$25 - 35,000 a piece.

Channel features

American Galvano

80um Best

10-15um Controlled Clearance.



mount to mold insert

need v. controlled
thickness for
detection
w/in 10um
of data
plane

electroforming not flat

Tried CVD. Looks awful.

Metal Master

To Page No. _____

Witnessed & Understood by me,

Date

Invented by

Date

Recorded by